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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,751	CHAR ET AL.	
	Examiner	Art Unit	
	GARY COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4-10, 12, 14-16, 20, 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 ,4-10, 12, 14-16, 20, 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/09/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. The amendment filed 02/09/11 is acknowledged and has been entered. Claims 2, 3, 11, 13, 17-19 and 21 are cancelled. New claim 28 has been added. Accordingly, Claims 1, 4-10, 12, 14-16, 20 and 22-28 are pending and under examination.

Withdrawn Rejections

2. All rejections of claims not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 4, 5, 7-10, 12, 16, 20 and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rech-Weichselbraun et al (US 2004/0171087) in light of Sawyer et al (US 5,602,041) and in view of Mitoma (Patent Abstracts of Japan, 63111467, 1988)(submitted in IDS filed 04/03/07) and Head et al., (Environmental Entomology, February 2002, Vol. 31, No. 1, pages 30-36).

Rech-Weichselbraun et al discloses a ready-to-use solid support, kits and methods of making and using the solid support. Rech-Weichsebraun et al disclose preparing microtiter plates (solid support) for use in detecting analytes in a sample (abstract, pgs 1-4). Rech-Weichselbraun et al disclose precoating the wells of the microtiter plate with antibody (abstract, para 0001, 0050-0053) specific for the analyte of interest. Rech-Weichselbraun et al disclose contacting the plate with a first antibody and washing with buffer such as phosphate buffer saline (e.g. para 0053-0054). Rech-Weichsebraun et al disclose blocking the plate by the addition of phosphate buffer

saline (stabilizer) and bovine serum albumin (para. 0056). As shown by Sawyer et al ('041) blocking reagents (stabilizers) such as bovine serum albumin and fish gelatin provide for stabilizing the specifically bound biomolecules and prevent denaturation that can result in loss of immunological or enzymatic activity (e.g col 1, lines 13-42). Rech-Weichsebraun et al disclose removing excess blocking reagent (stabilizer) (e.g. para 0059). Rech-Weichsebraun et al disclose drying the plate with a circulating drier (air-drying) (e.g. para 0059). Rech-Weichsebraun et al disclose that the wells of the plate additionally comprise the detection reagents in lyophilized form and disclose that mixtures of the detection reagents are added to the well and lyophilized (e.g. para's 0031-0035, p. 4). Rech-Weichsebraun et al disclose that the detection reagents can be a detection antibody (second antibody) and an enzyme-coupled antibody (third antibody) against the detection antibody (e.g. para 0046). Rech-Weichsebraun et al disclose storing the solid support and components in a kit (e.g. abstract, para 0029, pgs 3-4). Rech-Weichsebraun et al disclose that the microtiter plate can comprise polystyrene (para. 0048). Rech-Weichsebraun et al disclose the solid support can be used in ELISA methods for the detection of an analyte in a sample (e.g. para 0035, pgs 4-7). Rech-Weichsebraun et al disclose reconstituting the plates (e.g. pgs 4-7) and adding sample, incubating, washing, adding substrate and photometrically detecting the complexes (e.g. pgs 2-7). Rech-Weichsebraun et al discloses that the analyte can be proteins, steroids, chemical compounds, drugs, nucleic acids and similar substances (e.g. para. 0045).

Rech-Weichsebraun et al differs from the instant invention in failing to teach incubating the stabilizer at a temperature of 4 degrees Celsius. Rech-Weichsebraun et al also differs from the instant invention in failing to teach the first and second antibodies are antibodies which specifically recognize a Cry protein and also fails to teach the first antibody is a monoclonal antibody.

Mitoma teaches that it is known and conventional in the art of immunoassays to add bovine serum albumin blocking reagent (stabilizer)(same reagent as used by Rech-Weichsebraun et al) and incubate the blocking reagent (stabilizer) in the well at a temperature of between 2-25 degrees Celcius. Therefore, with respect to the 4 degree Celcius as recited in the instant claims, the optimum temperature for the blocking reagent (stabilizer) in the incubation step can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Head et al disclose ELISA methods for the detection of Cry1Ac protein (Cry protein) in a sample (e.g. pgs 31-32). Head et al discloses the use of monoclonal anti-

Cry1Ac capture antibodies (first antibody)(p. 31). Head et al discloses a secondary polyclonal rabbit anti-Cry1Ac antibody (p. 31) and a donkey anti-rabbit alkaline phosphate conjugate antibody (third antibody)(p.32). Head et al also teaches washing with ovalbumin phosphate buffer saline with the second and third antibodies to minimize potential matrix effects (e.g. p. 32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate first, second and third antibodies such as taught by Head et al into the modified method, kit and solid support of Rech-Weichsebraun et al because Rech-Weichsebraun et al is generic with respect to the protein that is to be detected and one would use the appropriate reagents i.e. capture and detection antibodies such as taught by Head et al to detect the desired protein, in this case Cry protein.

With respect to claims 23-27 as instantly recited Rech-Weichsebraun et al specifically teaches an embodiment wherein the microtiter wells comprise the first, second and third antibodies (see teachings supra) and specifically teaches that the second antibody (detection antibody) is specific for the analyte and teaches that the third antibody is labeled with enzyme and that this third antibody is specific for the detection antibody (see e.g. page 4, para 0046 "enzyme-coupled antibody against detection antibody"). Thus, Rech-Weichsebraun et al is teaching an embodiment wherein the support or method does not require biotin/streptavidin (sensitivity enhancer). Although, Rech-Weichsebraun et al also discloses embodiments wherein biotin and streptavidin are used in the detection process, Rech-Weichsebraun et al also

teaches the above embodiment of a third antibody labeled only with enzyme and the third antibody is specific for the second antibody (detection antibody). Also, one of ordinary skill in the art must consider all embodiments of a disclosure and it is well settled that a reference must be evaluated for all disclosures not just its preferred embodiments. *In re Mills,* 470 F. 2d 649, 176 USPQ 196 (CCPA 1972).

With respect to the incubation time of the stabilizer and the incubation time of the lyophilizing as recited in the instant claim, the optimum incubation times can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

With respect to the pH range of the phosphate buffers as recited in instant claims 4 & 5, the optimum pH of phosphate buffer can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rech-Weichselbraun et al in view of Mitoma and Head et al as applied to claims 1, 4, 5, 7-10, 12, 16, 20 and 22-28 above, and further in view of Vogt et al (Journal of Immunological Methods, 101, (1987) pgs 43-50).

See above for the teachings of Rech-Weichsebraun et al., Mitoma and Head et al.

Rech-Weichsebraun et al., Mitoma and Head et al differ from the instant invention in failing to teach the blocker (stabilizer) used is a mixture of phosphate buffered saline.

Vogt et al teaches that it is known in the art to utilize fish gelatin diluted with phosphate buffer (as a blocking reagent (e.g abstract, p. 45, p. 48) (thus teaches mixture of phosphate buffered saline) and teaches that this mixture is an excellent blocker and is readily available without need for further processing (e.g. p. 49) and provides higher inhibition than that of BSA (Table II, pg 48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a mixture of phosphate buffered saline and fish gelatin

such as taught by Vogt et al for the phosphate buffered saline and BSA of Rech-Weichsebraun et al because Vogt teaches that fish gelatin is an excellent blocker and is readily available without need for further processing and provides higher inhibition than that of BSA in Elisa assays.

8. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rech-Weichselbraun et al in view of Mitoma and Head et al as applied to claims 1, 4, 5, 7-10, 12, 16, 20 and 22-28 above, and further in view of Adang et al (US 6,586,197) in light of Biocompare, (The Buyers Guide for Scientists, April 2011).

See above for the teachings of Rech-Weichsebraun et al., Mitoma and Head et al.

Rech-Weichsebraun et al., Mitoma and Head et al differ from the instant invention in failing to specifically teach the third antibody is a polyclonal IgG antibody.

Adang et al teaches that it is known and conventional in the art to utilize donkey anti-rabbit IgG antibodies which are specific against rabbit antibodies (e.g. col 16, line 65 - col 17, line 28) (As shown by Biocompare, The Buyers Guide for Scientists the donkey anti-rabbit IgG antibodies of Adang et al are whole antibodies) (note: the Biocompare reference is from GE Healthcare, formerly Amersham Biosciencies (which provided the antibody in Adang)). Since, the antibody of Adang was produced within an animal which comprised different B cell resources the antibodies of Adang et al are polyclonal antibodies.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an antibody such as taught by Adang et al into the modified method, kit and solid support of Rech-Weichsebraun et al because Head et al is silent with respect to the specifics of the donkey anti-rabbit third antibody and Adang et al teaches that it is known and conventional in the art to use IgG whole donkey anti-rabbit antibodies which are specific for rabbit antibodies for detection purposes.

Response to Arguments

9. Applicant's arguments filed 02/09/11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/ Gary W. Counts/

Examiner, Art Unit 1641